K080532

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510(K) SUMMARY

NOV 12 2008

(As Required by Section 807.92 (c))

1. **Submitter**

Name:	Unicare Biomedical, Inc.
Address:	22971-B Triton Way, Laguna Hills, CA 92653
Contact:	Stan Yang, 949-643-6707
Date:	November 7, 2008

2. **Device Name**

Trade Name:	Benacel®
Common Name:	Hemostat Wound Dressing
Classification Name:	Dressing
Device Classification:	Unclassified
Product code:	FRO

3. **Predicate Devices**

Hemcon, Bloodstop

4. **Device Description**

Benacel® hemostatic gauze is made of oxidized regenerated cellulose material. Upon contact with blood or extrudate, Benacel® hemostatic gauze will absorb the fluid and expand, transforming into a gelatinous material. By applying gentle pressure at this time, the hemostatic gauze will adhere to the wound, sealing the ends of the bleeding capillaries. Benacel® hemostat is sterile packaged and supplied in a variety of configurations and sizes.

5. **Indications for Use:**

Benacel® is intended to be used as a topical dressing for local management of bleeding wounds, such as cuts, lacerations and abrasions, and for use as a temporary treatment of severely bleeding wounds, such as surgical wounds (operative, postoperative, donor sites, dermatalogical) and traumatic injuries.

6. Comparison with Predicate Devices

Benacel® is substantially equivalent to devices currently in U.S. commercial distribution, which are classified as wound dressing for control bleeding. Examples of such products include Hemcon® and Bloodstop®. These products are made of biocompatible materials with similar performance.

In vitro and in vivo tests demonstrate that Benacel's® performance is substantially equivalent to the predicate devices. Animal studies included in this submission show that Benacel® is equivalent to the cited predicate devices in the time it takes to achieve hemostasis. Thus Benacel® hemostatic gauze is substantially equivalent to the predicate devices in its intended use, biocompatibility and hemostatic performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Unicare Biomedical, Inc.
% Stan Yang, Ph.D.
Vice President
22971 Triton Way, Unit B
Laguna Hills, California 92653

Re: K080532
Trade/Device Name: Benacel
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 24, 2008
Received: October 30, 2008

NOV 12 2008

Dear Dr. Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): _____

Device Name: Benacel

Indications for Use:

Benacel® is intended for use as a topical dressing for local treatment of bleeding wounds, such as cuts, lacerations and abrasions. It may also be used for temporary treatment of severely bleeding wounds such as surgical wounds (operative, postoperative, donor sites, dermatalogical, etc.) and traumatic injuries.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080532

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)